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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

| EXAMINER | |
|---|---|
| TRAN, SUSAN T | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/630,633 | BREITENBACH ET AL. | |
| | Examiner | Art Unit | |
| | Susan T. Tran | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/523908 ('908). Although the conflicting claims are not identical, they are not patentably distinct from each other because application '908 claimed a transdermal therapeutic system (TTS) comprising a drug-containing hot-melt adhesive matrix produced by metering the drug into the solvent-free melt of the adhesive matrix at a temperature of 102°C-160°C. The TTS further comprises a drug and a softener (claims 28 and 31). Hot-melt adhesive includes amine-resistant silicone (claim 31). Softeners are found in claims 32 and 33. Drug include Rotigotine is found in

claims 28, 29 and 42-44. Amount of drug is found in claims 34-36. Drug present in form of a base is found in claim 37. Release profile is found in claims 46-48. Accordingly, the present claims are anticipated by the claims of the '908 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Objections*

Claims 5-10, 16, 17 and 21-23 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 10-13 are objected to because of the typographical errors. The claims do not contain a period "." at the end of the sentence. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a TTS comprising hot-melt adhesive matrix and Rotigotine, does not reasonably provide enablement for the release profiles recite in claims 14-16. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: breadth of the claims, nature of the invention, state of the prior art, amount of direction provided by the inventor, the level of predictability in the art, the existence of working examples, quantity of experimentation needed to make or use the invention based on the content of the disclosure, and relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors being discussed below:

*Breadth of the Claims*: is broad. Independent claim 14 is directed to a TTS of Rotigotine characterized in that for a period of at least 5 days following its application on human skin, the TTS induces in the patient an average plasma concentration of 0.4 to 2 ng per ml Rotigotine.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims 14-16 do not recite the structure of the TTS that contain any adhesive matrix and softener in the amounts that would result in the claimed release profiles.

*Amount of direction provided by the inventor*: the present specification discloses a specific TTS that exhibits the specific release profiles recite in the claims. See for example specification at pages 16-18, and examples. The TTS contains specific silicone-base hot-melt. The present specification, however, does not teach how to

precisely achieve the claimed release profiles given any TTS using any type of materials in any amount. This is further impossible in view of the multitudes of types of suitable transdermal polymers such as water-soluble, water-insoluble, and etc. The specification also fails to teach if all of the claimed properties can be achieved with all type of transdermal polymers in any amount, and in any structures. The specification does not provide any guidance as to how one can achieve the claimed specific release profile with any type of dosage structures, such as single layer, non-adhesive layer, multi-adhesive layer, pressure sensitive coating layer, and so on. Accordingly, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

As such, the practitioner would turn to trial and error experimentation in order to compose a TTS comprising Rotigotine, without guidance from the specification or the prior art.

*The relative skill of those in the art*: the skill of those in the art is very high, *e.g.*, Ph.D. or M.D. level technology.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 provides for the use of Rotigotine in the TTS, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 20 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 11-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Metman et al. (Clinical Neuropharmacology) and Noel US Re. 36,754.

Chen teaches a TTS comprising a backing layer, and an adhesive polymeric matrix which contains combination of a permeation enhancer and at least about 30% ropinirole or an analog thereof as an active agent (abstract; column 3, lines 1-37; column 4, lines 25-37; and column 6, lines 36-46). Permeation enhancer includes polyethylene glycol, propylene glycol, alcohol, and the like (column 7, lines 24-39). Active agent can be administered in the form of a base or pharmaceutically acceptable

salt (column 7, lines 6-10). The polymeric matrix further comprises pressure sensitive adhesive polymer including silicone (column 8, lines 48-67).

Chen does not expressly teach the claimed active agent.

Metman teaches transdermally administering rotigotine for the treatment of Parkinson's disease (abstract). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen to include rotigotine as an active agent in view of the teaching of Metman, because Metman teaches that rotigotine is an effective treatment for advanced Parkinson's disease with mild adverse effects compare to other active agent, because Metman teaches using rotigotine for the treatment of Parkinson's disease allows patients to substantially lower L-Dopa doses without loss of antiparkinsonian efficacy, and because Chen teaches the desirability to obtain a TTS useful for the treatment of Parkinson's disease.

Chen further does not teach the matrix system that comprises organic wax.

Noel teaches a hot-melt silicone-base TTS comprising silicone sensitive adhesive, and organic waxes having melting point between 30-150°C (abstract). Organic waxes include vegetable waxes, animal waxes, mineral waxes such as ozokerite, and mixtures thereof in an amount of from about 1 to about 25% (column 5, lines 1-11; and claim 17). Silicone sensitive adhesive is present in an amount from about 99-85% (column 8, lines 41-44). Noel further teaches the hot-melt silicone-base TTS is free of solvent (column 2, lines 66-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen using the hot-melt silicone-base TTS in view of the teaching of Noel to obtain the claimed invention. This is because

Noel teaches a transdermal system that is highly efficacious, because Noel teaches using organic waxes to decrease viscosity and improve coatability which do not require the present of solvents (column 1, lines 66 through column 2, lines 1-3), because Noel teaches using organic waxes over the use of solvents to avoid: 1) removal and containment of solvents, 2) special precautions to avoid fires, and 3) cost effectiveness (ID), because Chen teaches a TTS that comprises silicone and waxes as carriers (column 6, lines 25-27), and because Chen teaches the desirability to obtain a TTS that improved patient compliance and with less side effects (column 2, lines 51-60).

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615